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Proposed Re-evaluation Decision PRVD2015-03

Propamocarb

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the fungicide propamocarb, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing propamocarb for sale and use in Canada.

An evaluation of available scientific information found that products containing propamocarb do not present unacceptable risks to human health or the environment when used according to revised label directions.

This proposal affects all end-use products containing propamocarb registered in Canada. Once the final re-evaluation decision is made, the registrant will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for propamocarb and presents the reasons for the proposed re-evaluation decision.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of propamocarb.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, presents the details of the cyclical re-evaluation approach, which is in line with the requirements of the *Pest Control Products Act*.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

What Is Propamocarb?

Propamocarb is a protectant fungicide with systemic activity. It is registered for control of *Pythium* blight and damping off caused by *Pythium spp.* on turfgrass in golf courses and sod farms; downy mildew on cucurbits and lettuce; late blight on potato and tomato; *Pythium* root rot and damping off on greenhouse tomato, cucumber, peppers and eggplant; and *Pythium* and *Phytophthora* root rot on outdoor and greenhouse ornamentals. Propamocarb is formulated as suspension or solution, and is applied using groundboom, aerial, drench, drip irrigation, hand held and/or backpack application equipment.

Health Considerations

Can Approved Uses of Propamocarb Affect Human Health?

Propamocarb is unlikely to affect your health when used according to the label directions.

People could be exposed to propamocarb by consuming food and water, working as a mixer/loader/applicator, by entering treated sites, or by handling treated ornamentals. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Occupational mixer/loader/applicator exposure is not of concern for workers handling propamocarb according to the current label directions. Further, exposure to workers re-entering treated sites for various activities is not of concern on the day of application. Residential exposure to golfers playing on treated turf and homeowners handling commercially treated ornamentals was not of concern. Dietary exposure to propamocarb through consumption of domestic and imported food commodities and drinking water is not of concern. Currently registered labels include the required mitigation measures, no additional mitigation measures are proposed pertaining to human health exposure to propamocarb.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of adulterated food, in other words, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that is at or below the established MRL does not pose an unacceptable health risk.

MRLs for propamocarb have been established for registered and imported commodities.

Environmental Considerations

What Happens When Propamocarb Is Introduced Into the Environment?

Propamocarb is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target terrestrial and aquatic organisms could be exposed to propamocarb in the environment. Based on the risk assessment conducted by the PMRA, the currently registered uses of propamocarb are not of concern to earthworms and pollinators. However, there is a potential risk identified for birds, small wild mammals, terrestrial plants and amphibians from the use on turf. To minimize the potential risks to these organisms, the registered end-use product label for turf use includes environmental hazard statements and buffer zones.

Measures to Minimize Risk

No additional mitigation measures are proposed pertaining to human health or environmental exposure to propamocarb. However, labels are proposed to be amended as per the current labelling standard.

What Additional Scientific Information Is Required?

No additional data are required.

Next Steps

Before making a final re-evaluation decision on propamocarb, the PMRA will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on propamocarb. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Propamocarb is a protectant fungicide with systemic activity.

Following the re-evaluation announcement for propamocarb, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the label of end-use products in Canada.

Currently registered products containing propamocarb are listed in Appendix I.

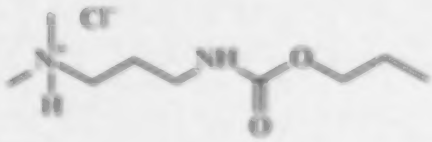
2.0 Use Description of Propamocarb

Propamocarb is registered for control of *Pythium* blight and damping off caused by *Pythium* spp. on turfgrass in golf courses and sod farms; downy mildew on cucurbits and lettuce; late blight on potato and tomato; *Pythium* root rot and damping off on greenhouse tomato, cucumber, peppers and eggplant; and *Pythium* and *Phytophthora* root rot on greenhouse and outdoor container ornamentals. Propamocarb can be applied by groundboom, aerial, drench, drip irrigation, handheld and/or backpack application equipment.

3.0 The Technical Grade Active Ingredient, Its Properties

3.1 Identity of the Technical Grade Active Ingredient

Common Name		Propamocarb Hydrochloride
Function		Fungicide
Chemical Family		Carbamate Fungicide
Chemical Name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	propyl 3-(dimethylamino)propylcarbamate hydrochloride
2	**Chemical Abstracts Service (CAS)**	propyl N-[3-(dimethylamino)propyl]carbamate hydrochloride (1:1)
CAS Registry Number		25606-41-1
Molecular Formula		$C_9H_{21}ClN_2O_2$

Structural Formula	
Molecular Weight	224.73
Purity of the Technical Grade Active Ingredient	72.1%
Registration Number	24543

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including Toxic Substances Management Policy (TSMP) Track 1 substances, are not expected to be present in the product.

3.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result	Interpretation
Vapour pressure at 20°C	3.85×10^{-7} mPa	Non-volatile
Ultraviolet (UV)/ visible spectrum	No significant absorption at $\lambda > 300$ nm	—
Solubility in water at 20°C	> 500 g/L (pH 1.6-9.6)	Very soluble in water
n-Octanol/water partition coefficient at 22°C	logP = -1.21 (pH 7) log K_{oc} = -2.6 log K_{oc} = 0.841	Bioaccumulation is unlikely
Dissociation constant (pKa)	9.3 at 20°C	—

4.0 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Exposure to propamocarb may occur through diet, working as a mixer/loader/applicator, by entering treated sites or by handling treated crops.

4.1 Toxicology Summary

Propamocarb has low acute toxicity by the oral, inhalation and dermal routes. It is minimally irritating to the eyes and skin. Propamocarb is considered to be a potential skin sensitizer in humans. Label statements for skin sensitization potential are proposed for consistency (existing on several labels). No neurotoxic concerns were identified in an acute neurotoxicity study.

In the subchronic and chronic studies, effects on body weight (body-weight gain at the mid and high doses, often correlated with a decrease in food consumption and food efficiency) were observed. The liver, stomach, eyes and brain were identified as target organs.

Propamocarb was not determined to be carcinogenic in rats and mice. No evidence of mutagenic potential was observed in any of the reviewed genotoxicity studies. Propamocarb did not cause adverse reproductive effects nor did it cause malformations.

4.2 *Pest Control Products Act* Hazard Considerations

For assessing risks from potential residues in food or from products used in or around residential areas or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects. This factor should take into account potential pre- and post-natal toxicity and completeness of the data with respect to the exposure of, and toxicity to, infants and children. A different factor may be determined to be appropriate on the basis of reliable scientific data.

The toxicity database for propamocarb was considered complete and was considered adequate for the assessment of risk to infants and children. Data available include a one-generation reproduction study, multi-generation reproduction studies in rats, and developmental toxicity studies in rats and rabbits.

With respect to potential pre- and post-natal toxicity, there was no indication of increased susceptibility in the offspring compared to parental animals. Offspring toxicity (decreased pup body weights and food consumption) occurred at doses causing parental toxicity (decreased body weights and body-weight gains) in the reproductive studies. No adverse effects were observed on reproduction, and there was no evidence of sensitivity of the young. Signs of fetotoxicity and increased post-implantation loss were observed in the developmental rabbit study at the same doses that caused decreased body-weight gain or body weight in the dams. It is not clear if the increase in abortions and resorptions was maternally or fetally mediated in the rabbits, however, the effect is considered serious (late death in the form of abortion), with an increased incidence of early resorptions at the higher dose). Early resorptions, decreases in mean fetal weight and minor skeletal anomalies also occurred in a rat developmental study, but at the same dose that caused significant maternal toxicity.

In consideration of the information presented above, the *Food Uncertainty Factor* factor was reduced from 10-fold to 3-fold when using the rabbit developmental toxicity studies for risk assessment for dermal and inhalation exposure for short- to intermediate-term scenarios. The *Food Uncertainty Factor* factor is reduced to one-fold for other scenarios.

Appendix II provides an overview of toxicology endpoints for propamocarb used in human health risk assessments by the PMRA.

6.3 Dermal Absorption

Based on a chemical-specific in vivo dermal absorption study, a dermal absorption factor of 20.4% was determined for risk assessment purposes for propamocarb.

6.4 Occupational Exposure

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

Workers can be exposed to propamocarb through mixing, loading and by application using various types of application equipment or when entering a treated site to conduct activities such as scouting and/or handling of treated crops.

The currently registered product labels require that workers must wear long pants, long-sleeved shirts and boots during all activities. In addition, during mixing, loading, cleanup and repair activities, workers must also wear chemical-resistant gloves and safety goggles or a face shield.

6.4.1 Mixer/Loader/Applicator Exposure and Risk

Mixer/loader/applicator exposure is expected to be mainly via dermal and inhalation routes.

Based on propamocarb use pattern, the following scenarios were assessed:

- Short- and intermediate-term exposure from open mixing/loading and groundboom application (open cab) to potato, field tomato, cucurbits and lettuce.
- Short- and intermediate-term exposure from open mixing/loading and aerial application to potato.
- Short- and intermediate-term exposure from open mixing/loading and groundboom (open cab), backpack or turf gun application to turf (sod farm and golf courses).
- Short- and intermediate-term exposure from open mixing/loading and irrigation, manually pressurized handwand or backpack foliar application to greenhouse cucumber.
- Long-term exposure from open mixing/loading with drench/drip irrigation, backpack sprayer or manually pressurized handwand soil application to greenhouse tomato, pepper, cucumber and eggplant.

- Long-term exposure from open mixing/loading with downslope irrigation or manually pressurized backpack soil application to ornamentals (greenhouse and outdoor)

The mixer/loader/applicator exposure assessment was based on workers wearing the personal protection equipment specified on the current registered labels, and applied at the maximum registered application rates for each crop. The potential dermal and inhalation exposures were estimated using data from the Pesticide Handlers Exposure Database (PHED), Version 1.1.

Short- and intermediate-term combined dermal and inhalation exposure is not of concern for the assessed scenarios. For long-term scenarios, the combined dermal and inhalation exposure is also not of concern for the assessed scenarios. Therefore, no further mitigation measures are proposed.

6.6.2 Post-application Exposure and Risk

For workers entering treated fields to conduct post-application activities, dermal exposure is considered to be the primary route of exposure. Propamocarb is relatively non-volatile with a low vapour pressure of 2.0×10^{-7} mmHg at 25°C, meeting the North American Free Trade Agreement (NAFTA) criterion for an inhalation waiver based on low volatility due to a vapour pressure of less than 7.5×10^{-7} mmHg (NAFTA, 1999). Therefore, inhalation exposure is considered to be negligible for outdoor post-application activities compared with dermal exposure.

Post-application occupational risk assessments consider dermal exposure to workers entering treated sites to conduct agronomic activities involving foliar or soil contact. Based on the propamocarb use pattern, there is potential for short- (< 30 days) to long-term (6+ months) exposure.

For foliar and turf contact, potential exposure of post-application workers was estimated using activity-specific transfer coefficients and dislodgeable foliar residue (DFR) or transferable turf residue (TTR) values. The DFR/TTR refers to the amount of residue that can be dislodged or transferred from a surface, such as leaves of a plant. The TC is a measure of the relationship between exposure and DFRs for individuals engaged in a specific activity, and is calculated from data generated in field exposure studies. The transfer coefficients are specific to a given crop and activity combination and reflect standard agricultural work clothing worn by adult workers. Post-application exposure activities include mechanical weeding, mowing, thinning, pruning, scouting, irrigating and harvesting.

For contact with treated soil (soil drench/irrigation), post-application exposure was estimated based on the potential concentration of propamocarb in soil and the expected adherence and dissolution to skin from handling treated soil.

Based on the maximum registered application rates and application intervals, short- and intermediate-term post-application exposure (field vegetables, turf, outdoor ornamentals) is not of concern on the day of application for all assessed uses and handler activities. Long-term post-application exposure (greenhouses) is also not of concern on the day of application for all assessed uses and handler activities.

All required mitigation measures (such as restricted entry intervals) are already on the registered labels. No additional risk mitigation measures are proposed for post-application exposure. Revised wording is required on certain labels for re-entry during the restricted-entry interval period to meet the current label standard.

4.5 Non-occupational Exposure

The non-occupational (residential) risk assessment estimates the risk to the general population, including children/youths, during or after pesticide application.

4.5.1 Dietary Exposure and Risk

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in milk and meat, may be ingested with the daily diet (food and drinking water). Exposure to propamocarb from potentially treated imports is also included in the assessment. These dietary assessments are age-specific and incorporate the different eating habits of the population at various stages of life. For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults.

Plant and animal metabolism of propamocarb is adequately understood. Analytical methods for determination of residues in plants and animals were considered adequate. Storage stability data are available to support the sample storage conditions. Supervised residue trials are available for representative crops to support the registered uses.

The residue definition of propamocarb in plants is the parent, propyl [3-(dimethylamino)propyl]carbamate hydrochloride; in animals, the residue definition is the parent, and the metabolites AE F155306, AE F132675, AE F132679 and propamocarb glucuronide for enforcement and risk assessment purpose.

An acute dietary assessment was not required as an acute reference dose (ARfD) has not been identified for propamocarb.

The chronic dietary risk was calculated by estimating the consumption of different foods and the residue values on those foods. This expected intake of residues was then compared to the acceptable daily intake (ADI). When the expected intake of residues is less than the ADI, then chronic dietary exposure is not of concern. The chronic dietary assessment was refined at the intermediate level using median values from residue field trial data and experimental processing factors where available. Chronic dietary exposure from all supported (import and domestic) propamocarb food uses for the representative population subgroups ranged from

7.1 to 9.7 % of the ADI. Levels in drinking water were estimated based on the field use of propamocarb on turf at a maximum rate of 13.86 kg a.i./ha/year (expected environmental concentration of 58 µg a.i./L, surface water, level I). The estimated drinking water value is conservative to levels of propamocarb detected in the available water monitoring information. Chronic dietary exposure to propamocarb from food and drinking water ranged from 7.9 to 11.2% of the ADI for all subpopulations. The lowest exposed population subgroup was children less than one year old; the highest exposed population subgroup was children 3-5 years old. On this basis, chronic dietary exposure to propamocarb from food and drinking water is not of concern.

A cancer assessment was not required as propamocarb is not carcinogenic.

4.5.2 Residential Exposure and Risk

There are no domestic class products containing propamocarb registered in Canada, therefore, residential mixer/loader/applicator risk assessment was not required.

4.5.2.1 Exposure and Risk for Golfers

There is potential for short- to intermediate-term exposure to golfers exposed to freshly treated turf. Exposure to golfers was estimated using TTR values and transfer coefficients representative of typical golfing activities for adult, youth and child golfers.

The estimated exposure for golfers contacting treated turf was not of concern on the day of application.

4.5.2.2 Exposure and Risk for Handlers of Ornamentals

Propamocarb is registered for greenhouse and outdoor container grown ornamentals. Residential short- and intermediate-term exposure through handling treated ornamentals and soil is possible. Post-application exposure was estimated based on the potential concentration of propamocarb in treated soil and the expected adherence and absorbance to skin.

The estimated exposure from handling treated ornamentals was not of concern.

4.5.2.3 Exposure and Risk for Bystanders

Potential for bystander exposure is considered minimal and is expected to be significantly less than exposures estimated for workers. Based on the worker risk assessment, bystander exposure is not expected to be of concern.

4.6 Aggregate Exposure and Risk

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation).

Aggregate exposure from food and water is considered acceptable and below the level of concern for all population subgroups. The lowest exposed population subgroup was children less than one year old; the highest exposed population subgroup was children 3-5 years old (< 12% of ADI). No acute or cancer aggregate food and water assessment is required for propamocarb.

Based on the exposure estimates for golfers (MOE > 3000, target MOE of 300) and from handling treated ornamentals (MOE > 40,000, target MOE of 300), and considering exposure from food and drinking water (< 12% of the ADI), it is not expected that aggregate exposure (from food, drinking water and residential exposure) would result in risks of concern.

4.7 Cumulative Exposure and Risk

No common mechanism of toxicity has been found with other pest control products. Therefore, no cumulative risk assessment was conducted during the re-evaluation.

5.0 Environment

5.1 Environmental Fate

Propamocarb is stable to hydrolysis and undergoes limited phototransformation (half-life of 35.4 days on soil). Laboratory biotransformation studies have shown that propamocarb is generally non-persistent in aerobic soils, although some studies have shown that this compound may be slightly persistent in some types of soil (overall, the aerobic half-life ranged between 10 and 44 days; corresponding DT_{90} values ranged from 14 to 63 days). Under field conditions, propamocarb was found to be non-persistent in soil (half-life of 9 days; DT_{90} of 23 days). Propamocarb will, however, persist in anaerobic soils (half-life of 459 days; corresponding DT_{90} of > 4 years). No major transformation products are formed in soil.

The mobility of propamocarb was found to be variable. Results from adsorption/desorption studies indicated that propamocarb could have a high mobility in some soils but could be immobile in others. Results from soil column leaching studies were also variable. In some studies, low concentrations of propamocarb were found in leachates (between ≤ 0.07% and < 2%), suggesting a very low potential for leaching. However, in other studies, up to 48% of propamocarb was found in leachates. Drinking water modelling results indicate that propamocarb could reach groundwater. In field studies on turf, however, there was minimal movement of propamocarb to the lower layers of the soil profile. There is limited water monitoring data available. One water monitoring study in Canada that analyzed 53 samples over 3 years indicated no detection of propamocarb in groundwater.

Propamocarb may enter surface water through spray drift and/or runoff. Abiotic processes such as hydrolysis and phototransformation will not affect the degradation of propamocarb in aquatic systems (this compound is stable to hydrolysis and no phototransformation occurred in a laboratory study over a period of 22 days). Propamocarb is slightly persistent in aerobic aquatic systems (in tests performed in aerobic water/sediment systems, the whole system half-life was 23 and 35 days; corresponding DT_{90} values were 75 and 64 days) but is more persistent under anaerobic aquatic conditions (under these conditions, the biotransformation is biphasic with a

whole system half-life of 50 days for the first phase and 94 days for the second; corresponding DT_{90} was 260 days). No major transformation products are formed in water. Updated label statements to limit runoff and contamination of aquatic sites are required for all propamocarb products.

Based on the log K_{ow} for propamocarb (-2.6 and 0.841, depending on the study), this compound is unlikely to bioaccumulate. This is consistent with results from bioaccumulation studies, which showed a rapid elimination from fish tissue (depuration half-life of 3 days; DT_{90} of 14 days).

Based on the vapour pressure and Henry's law constant, propamocarb has a low potential for volatilization.

5.2 Environmental Exposure and Risk Assessment

Based on the propamocarb use-pattern, application to turf was considered to be the worst-case scenario for environmental exposure.

5.2.1 Terrestrial Species

Propamocarb is not acutely toxic to earthworms, honeybees (oral and contact) and other non-target arthropods (spider, hover fly, rove beetle and carabid beetle). Propamocarb has no detrimental effects on seed germination and vegetative vigour in non-target plants; however, negative effects were observed on seedling emergence. Potential risk to terrestrial organisms from uses on field crops, greenhouse vegetables, and greenhouse and outdoor ornamentals were determined to be not of concern. Use on turf could pose a risk to birds and small wild mammals (on an acute dietary and reproductive basis), and non-target plants. Current registered end-use labels for turf use includes environmental hazard statements and buffer zones to minimize the potential risk to non-target organisms.

5.2.2 Aquatic Species

Propamocarb is slightly toxic to aquatic invertebrates on an acute basis. Chronic effects (survival and reproduction) were observed in *Daphnia magna*. Propamocarb is practically non-toxic on an acute basis to freshwater and marine fish. No treatment-related effects were observed in a chronic toxicity test with rainbow trout; however, negative effects on weight and length of fish were noted in an early life-stage toxicity test with fathead minnow. Toxicity to amphibians was extrapolated from the most sensitive fish species. The growth rate, biomass and yield of green algae were adversely affected by propamocarb.

5.2.3 Conclusion

Overall, risks to aquatic species from the use of propamocarb on turf are minimal. However, a potential chronic risk to amphibians from direct overspray was identified. Current labels for turf uses include a statement regarding the potential risk to amphibians (aquatic species) and the requirement for an aquatic buffer zone of one metre around sensitive habitats.

Current labels of registered products have the required risk mitigation measures to protect terrestrial and aquatic organisms and no additional risk mitigation measures are proposed.

Revised environmental hazard label statements to limit runoff and contamination of aquatic sites are proposed for all product labels.

6.0 Value

Propamocarb is a protectant fungicide with systemic activity. It belongs to the carbamate group of fungicides. The proposed biochemical mode of action of propamocarb is disruption of the formation of fungal cell membrane by interfering with synthesis of phospholipids and fatty acids. It reduces mycelial growth and development of sporangia and spores. It is absorbed by roots and leaves, and transported acropetally. Propamocarb is important for the control of water mold fungi (Oomycetes), which may cause diseases such as *Pythium* root rot and downy mildews on greenhouse vegetables. It is also important for the control of *Phytophthora infestans*, the pathogen of late blight on potato and tomatoes. Propamocarb can be rotated with other fungicides from different mode of action groups that control the same pathogen in an Integrated Pest Management program. This will not only prolong the effective life of propamocarb, but also enhance the effective life of other alternative single-site mode of action fungicides.

7.0 Pest Control Product Policy Considerations

7.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy: persistent [in air, soil, water and/or sediment], and bioaccumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*).

Propamocarb was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. It was concluded that propamocarb does not meet TSMP Track-1 criteria.

7.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of propamocarb, contaminants in the technical grade active ingredient are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[3] The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including DIR99-03 and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

- Technical grade propamocarb does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

8.0 Incident Reports

Starting 26 April 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame.

As of 25 July 2014, the PMRA has received one environmental incident report for this active ingredient. It was classified as minor in severity. The effects observed were considered unrelated to propamocarb exposure.

The United States Environmental Protection Agency (USEPA) Ecological Incident Information System (EIIS) was queried for environmental propamocarb incidents. There was one incident report available in the EIIS database related to damage to sugar beets.

9.0 Organization for Economic Co-operation and Development Status of Propamocarb

Canada is a member of the Organisation for Economic Co-operation and Development (OECD).

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries.

Propamocarb is currently acceptable for use in other OECD countries, including the United States, Australia and European Union Member States. As of 22 December 2014, no decision by an OECD member country to prohibit all uses of propamocarb for health or environmental reasons has been identified.

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[3] *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

10.0 Proposed Re-evaluation Decision

The PMRA has determined that products containing propamocarb for sale and use in Canada are acceptable for continued registration. Appendix III lists label amendments.

11.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, and DACO tables (datacode tables) can be found on the Pesticides and Pest Management portion of Health Canada's website. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP is available through the Environment Canada website.

List of Abbreviations

ADI	acceptable daily intake
a.i.	active ingredient
ARfD	acute reference dose
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetre(s)
DACO	data code
DFR	dislodgeable foliar residue
EIIS	Ecological Incident Information System
EP	end-use product
g	gram(s)
ha	hectare(s)
IPM	integrated pest management
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	octanol–water partition coefficient
LC_{50}	lethal concentration to 50% (a concentration causing 50% mortality in the test population
LD_{50}	lethal dose to 50% (a dose causing 50% mortality in the test population)
m	metre(s)
mg	milligram(s)
MOE	margin of exposure
MRL	maximum residue limit
NAFTA	North American Free Trade Agreement
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
pKa	-log10 acid dissociation constant
PMRA	Pest Management Regulatory Agency
PRVD	Proposed Re-evaluation Decision
ppm	parts per million
REI	restricted entry interval
TC	transfer coefficient
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
TTR	turf transferable residue
USEPA	United States Environmental Protection Agency

Appendix I Registered Products Containing Propamocarb as of 22 December 2014

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
24543	TGAI	Bayer CropScience Inc.	Propamocarb HCl Technical	Solution	72.1%
24915	Manufacturing Concentrate	Bayer CropScience Inc.	Tattoo Manufacturing Use Product	Suspension	375 g/L[1]
24544	Commercial	Bayer CropScience Inc.	Tattoo Suspension Concentrate Fungicide	Suspension	375 g/L
26288	Commercial	Bayer CropScience Inc.	Previcur N Aqueous Solution Fungicide	Solution	722 g/L
29156	Commercial	Bayer CropScience Inc.	Banol	Solution	722 g/L
29554	Commercial	Bayer CropScience Inc.	Tattoo Fungicide	Solution	722 g/L

[1] Co-formulated with chlorothalonil with a guarantee of 375 g/L.

Appendix II Human Health Toxicity Endpoints for Propamocarb

Exposure Scenario	Dose[a] (mg/kg bw/day)	Study	Target MOE[b]
Chronic dietary	12	Chronic toxicity and oncogenicity study in mice	
	ADI = 0.12 mg/kg bw/day, UF[c] = 100× (10 interspecies, 10× intraspecies)		
Acute dietary, general population			
	ARfD: No acute reference dose established		
Short- and intermediate-term dermal[d]	140	Developmental toxicity study in rabbits	300 (PCPA factor = 3.6/40)
Short- and intermediate-term inhalation	140	Developmental toxicity study in rabbits	300 (PCPA factor = 3.6/40)
Long-term dermal[d]	12	Carcinogenicity study in mice	100
Long-term inhalation	12	Carcinogenicity study in mice	100
Cancer	Propamocarb is not carcinogenic		

[a] NOAEL = no observed adverse effect level; ADI = acceptable daily intake; ARfD = acute reference dose

[b] MOE = margin of exposure

[c] UF = uncertainty factor

[d] A dermal absorption factor of 26.8% was used in a route-to-route extrapolation

[redacted] Label Amendments for Products Containing [redacted]

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, storage, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the above label statements.

Submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

1. For end-use products, Reg. Nos. [redacted], and [redacted], on primary panel, add the following statement:

   "Potential skin sensitizer"

2. For all end-use products, in the section entitled [redacted], add the following statement:

   "Potential skin sensitizer"

3. For end-use product, Reg. No. [redacted],

   a. Change the section title "[redacted]" to "[redacted]"

   b. Remove all statements related to greenhouse use:

      - Sections on [redacted]

        - "DO NOT allow effluent or runoff from greenhouse containing this product to enter lakes, streams, ponds or other waters."

      - Section [redacted] for [redacted] Applications on Commercial Sod Farms, modify the last sentence as follows:

        - "This worker protection statement provides for the protection of agricultural workers and handlers of agricultural pesticides."

   c. In the section entitled [redacted], modify the [redacted] as the following:

      "Field sprayer application: [redacted] apply during periods of dead calm. Avoid application of this product when winds are gusty. [redacted] apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572) medium classification. Boom height must be 60 cm or less above the crop or ground.

Buffer Zones

Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands) and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Method of Application	**Crop**	***Buffer Zones* (Metres) Required for the Protection of**	
		Freshwater Habitat	**Terrestrial Habitat**
Field Sprayer	Turf	1	1

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners."

4. The following statements are required for all products registered for outdoor uses under a section entitled **Environmental Hazards:**

"To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay."

"Avoid application when heavy rain is forecast."

"Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body."

5. The following statements are required for all products under a section entitled **Directions for Use**:

"As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests."

"DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."

6. For end-use product, Reg. No. 26288, replace the section entitled **Re-Entry Restrictions, For Soil Directed Applications to Ornamentals**:

"**DO NOT** enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours. This worker protection restriction provides for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment and restricted entry interval.

For Drench Applications: This worker protection restriction allows workers to enter the treated areas following application provided there will be no contact with any treated foliage. Personal protective equipment required for early entry to treated areas that is permitted under this worker protection restriction and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material.
- Shoes plus socks"

With

"**DO NOT** enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours."

References

Studies Considered in the Chemistry Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

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1774182	1986, PHY-BCJ-2 - On the Occurrence of [CBI REMOVED] in Previcur N, DACO: 2.13
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1774189	1990, PHY-BCJ-2 - Propamocarb Hydrochloride - Melting Point, DACO: 2.14.4
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Studies Considered in the Value Assessment

A. ADDITIONAL INFORMATION CONSIDERED

Published Information

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